

## REMARKS

Claims 1-6, 8-24, and 26-37 are currently pending. Applicants note that all amendments of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>1</sup> and without waiving the right to prosecute the amended Claims (or similar Claims) in the future.

In the Final Office Action dated 11/17/04, the Examiner made a number of rejections. The rejections are listed below in the order in which they are herein addressed.

(1) Claims 1-6, 8-20, 22-24, and 26-33 are rejected under 35 U.S.C. § 103 as allegedly being obvious in light of Chong et al. (Rapid Commun. Mass Spectrometr 12:1986 [1998]); hereinafter Chong) in view of Richmond et al (Richmond et al., J. Chromatography 835:29 [1999]; hereinafter Richmond);

(2) Claims 35-37 are rejected under 35 U.S.C. § 103 as allegedly being obvious in light of Chong taken in view of Richmond and further in view of Pandey et al. (Nature 405: 837 (2000); hereinafter Pandey); and

(3) Claims 1-6, 8-24 and 26-34 are rejected under 35 U.S.C. § 103 as allegedly being obvious in light of Chong taken in view of Richmond and further in view of Verentchikov (U.S. Patent 6,534,764; hereinafter Verentchikov).

### The Claims are not obvious

Claims 1-6, 8-20, 22-24 and 26-33 stand rejected under 35 U.S.C. § 103 as allegedly being obvious in light of Chong and Richmond (Office Action, pg. 2), Claims 35-37 as allegedly being obvious in light of Chong taken in view of Richmond and further in view of Pandey, and Claims 1-6, 8-24 and 26-34 as allegedly being obvious in light of Chong taken in view of Richmond and further in view of Verentchikov. The Applicants respectfully disagree. The Applicants submit that the examiner has failed to provide a prima facie case of obviousness. The

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<sup>1</sup> 65 Fed. Reg. 54603 (Sept. 8, 2000).

combination of references referred to by the Examiner fails to provide a *prima facie* showing of obviousness as required by § 2143 of the Manual of Patent Examining Procedure (MPEP). There are three criteria that must be met to provide *prima facie* obviousness. The first of these criteria is a suggestion or motivation in the references or the knowledge generally available to combine the reference teachings. The second criterion is that the prior art must teach or suggest all the claim limitations. The third criteria is a reasonable expectation of success should the combination be carried out. The Examiner has failed to provide a *prima facie* case of obviousness because these criteria have not been met.

#### **A. Failure to Properly Consider Rebuttal Evidence**

In the response to the Office Action dated 5/18/04, the Applicants presented reasons why the Examiner had and has continued to fail to provide a *prima facie* case of obviousness. It is Applicants' position that no additional evidence was needed. However, the Applicants provided rebuttal evidence in the form of a declaration by Dr. David Lubman. In the present Final Office Action, the Examiner has failed to properly address both the Applicants showing of lack of *prima facie* obviousness, as well as the declaration of Dr. Lubman. The Applicants submit that the Examiner must provide such evidence.

In particular, in response to the declaration by Dr. Lubman, the Examiner states "the expert opinion of David. M. Lubman in the declaration under 37 C.F.R. 1.132 is inadequate to overcome the rejection of claims 1-6, 8-24, and 26-34 based upon the cited prior art of Chong et al. in view of Richmond et al. further in view of Pandey et al. because there is no factual evidence supporting the statement. That is the expert opinion by David M. Lubman fails to set forth facts that the cited prior art does not include...." (Office Action, pg. 7). The Applicants disagree with the Examiner's statement. The Examiner goes on to list the facts that Dr. Lubman provided in his declaration, directly contradicting the prior statement. The Applicants submit that Dr. Lubman's declaration provides a listing of the specific claim elements **not** taught by the prior art cited by the Examiner (i.e., Dr. Lubman explains from a scientific perspective what is absent from a reading of the cited references). Dr. Lubman's factual statements provide direct and un-contradicted evidence as to why there is no motivation to combine the prior art references and why, even if combined, the references do not provide the claimed invention. The Examiner

has not rebutted this factual evidence provided in the declaration. As such, the Applicants submit that the Examiner has failed to properly consider the declaration of Dr. Lubman. The Applicants respectfully request that the Examiner consider the declaration of Dr. Lubman and either withdraw the rejection or provide evidence in support of the rejection.

**B. Claims 1-6, 8-24 and 26-34 are not Obvious**

The Examiner has further rejected Claims 1-6, 8-24 and 26-34 as allegedly being obvious in light of Chong and Richmond and further in view of Verentchikov. The Applicants respectfully submit that Examiner has failed to provide a motivation to combine the references to arrive at the presently claimed invention. Details of the Applicants' response to the Examiner's alleged case of *prima facie* obviousness are described in the Applicants' previous responses (the text of these responses is not repeated here, but is incorporated by reference to the prior responses of the Applicants). For example, Richmond provides no teaching that the display methods that Richmond applies to chemical samples be used in the display of protein samples, let alone multiple protein samples. This is in direct contrast to Chong and the present invention, which are directed towards analysis of **proteins** (See e.g., Claim 1).

Furthermore, as the Examiner has admitted (Office Action dated 5/18/04, pg. 3), Chong does not suggest the need for an alternate display method (*i.e.*, there is no basis in Chong or Richmond that would lead one to even contemplate modification of Chong as suggested by the Examiner).

Verentchikov solves none of the deficiencies of Chong or Richmond described above. For example, Verentchikov does not describe the need for separation steps prior to mass spectroscopy. As such, the addition of Verentchikov does not further support the Examiner's alleged case of *prima facie* obviousness.

It therefore appears that the Examiner is attempting to find the required motivation to combine the cited references in Applicants' own specification rather than in the cited art. Specifically, to arrive at the presently claimed invention, one of ordinary skill in the art would have had to have been motivated to: (I) choose the separation methods of Chong, while ignoring the fact that Chong says nothing about (and, indeed, is not at all concerned with) an alternative display method; and combine these elements with (II) the display method of Richmond, while

ignoring the fact that Richmond does not teach or suggest the use of the described methods for display of proteins; and (III) the mass spectrometry methods of Verentchikov, while ignoring the fact that Verentchikov is silent on the need for separation of samples prior to analysis. Without using the presently claimed invention and the present specification as the blueprint for this hindsight picking and choosing the isolated elements of each reference, one of ordinary skill in the art would have found no specific suggestions to include one element and exclude another from each of the cited references to produce the presently claimed invention. Without such suggestions in the cited art, the combination of the cited references as the Examiner has done is nothing more than a hindsight obviousness analysis.

As the Federal Circuit has held numerous times, however, such a hindsight analysis is impermissible -- instead, the Examiner must show suggestions, explicit or otherwise, that would compel one of ordinary skill to combine the cited references in order to make and use the claimed invention. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985) ("When prior art references require selective combination by the [fact-finder] to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself."); *Fine*, 5 USPQ2d at 1600 ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."); *In re Pleuddemann*, 910 F.2d 823, 828 (Fed. Cir. 1990) (noting that use of an applicant's specification as though it were prior art to support an obviousness determination is legal error); *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (holding that both the suggestion to combine references, and a reasonable expectation of success in making the claimed invention, "must be founded in the prior art, not in the applicant's disclosure."). The Board has also provided the same mandate on this issue:

it is impermissible to use the claimed invention as an instruction manual or "template" to piece together isolated disclosures and teachings of the prior art so that the claimed invention may be rendered obvious . . . a rejection based on § 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis.

*Ex parte Haymond*, 41 USPQ2d 1217, 1220 (Bd. Pat. App. Int. 1996). Thus, the use of hindsight analysis in the present case is impermissible and cannot be used to attempt to establish a *prima facie* case of obviousness. Applicants also are well-aware of the often-cited language in the MPEP that:

[a]ny judgement [sic] on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper.

MPEP § 2145(X)(A) (quoting *In re McLaughlin*, 443 F.2d 1392, 1395, 170 USPQ 209, 212 (C.C.P.A. 1971)). This boilerplate from the MPEP, however, does not negate the Examiner's burden of providing *specific* evidence or knowledge that would have motivated one of ordinary skill to have modified the cited references and combine their respective disclosures so as to arrive at the presently claimed invention. As noted above, such specific evidence or knowledge has not been provided by the Examiner; hence, the boilerplate language from the MPEP is of no avail in the present case.

Moreover, it is axiomatic that, in order to support a *prima facie* case of obviousness, the prior art must suggest making the *specific* modifications necessary to achieve the claimed invention. See *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995); *In re Lalu*, 747 F.2d 703, 705 (Fed. Cir. 1984) ("[t]he prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound."). That is, simply because "one can conceive a general process in advance for generating an *undefined* method [*e.g.*, separating, proteins, and displaying proteins] does not mean that a claimed *specific* method [*e.g.*, the specific methods of the presently claimed invention] was precisely envisioned and therefore obvious." *Deuel* at 1559. Thus, in order for Chong, Richmond, and Verentchikov to be suitable as primary references upon which to base a *prima facie* case of obviousness, there must be, at a minimum, a teaching or suggestion in these references that would have compelled one of ordinary skill in the art to include all of the elements of the presently invention in the combination of the presently claimed invention. As noted above, such a teaching or suggestion is wholly lacking in Chong, Richmond, and Verentchikov. Therefore, the cited references taken together are seriously deficient (particularly in view of the holding in *Deuel*), and cannot support

a *prima facie* case of obviousness.

Finally, Applicants are aware that the Examiner may consider the motivation to combine the cited references as "inherent" in the knowledge of one of ordinary skill in the art. Applicants wish to remind the Examiner, however, that there is no such thing as "inherent obviousness," since inherence and obviousness are different legal concepts. *See In re Spormann*, 150 USPQ 449, 452 (C.C.P.A. 1966). That which is inherent cannot be obvious, since inherent information "is not necessarily known . . . [and] Obviousness cannot be predicated on what is unknown." *Id.* Since the present rejection is based on obviousness, any contention by the Examiner that is based on the possible presence of inherent knowledge in the art (either in the cited references, or in the general knowledge of those of ordinary skill) must necessarily fail.

Applicants submit that, upon careful analysis of the cited references, the skilled artisan would have found no motivation to combine or modify the disclosures of the references to arrive at the presently claimed invention. Accordingly, a *prima facie* case of obviousness has not been established. Therefore, the rejection of the present claims under 35 U.S.C. § 103(a) is in error, and Applicants respectfully request that it be reconsidered and withdrawn.

The Applicants further submit that even if Chong, Richmond and Verentchikov are improperly combined, they do not teach all of the elements of the presently claimed invention. In particular, neither Chong nor Richmond nor Verentchikov, alone or in combination, teach the claim element of a protein profile map that displays protein abundance and mass of a separated protein sample. In addition, neither Chong nor Richmond nor Verentchikov, even if the teachings of the two references are improperly combined, provide a teaching of a **side by side** display showing **both** protein mass and abundance of multiple samples.

Furthermore, the Examiner has pointed to no teaching in Chong, Richmond or Verentchikov, alone or in combination, of the elements of dependent claims 13 or 21. For example, the Examiner has pointed to no teaching (nor is any present) in Chong or Richmond of the claim element of a switchable, multichannel valve (Claims 13 and 33) with the methods of the presently claimed invention. In rebuttal, the Examiner merely recites the Applicants definition of a switchable, multichannel valve (Office Action, pg. 3), but fails to specifically describe how the cited art teaches a valve that allows multiple apparatuses to be connected to one sample handler. The Examiner continues to cite the dual pump system described in Chong as a

"switchable, multichannel valve" without pointing to specific support for a valve that allows **multiple apparatuses** to be connected to **one sample handler**. Verentchikov further does not teach such a valve. As such, the Applicants submit that neither Chong, nor Richmond, nor Verentchikov, alone or in combination, teach the claim element of a switchable, multichannel valve for use in delivering sample from one apparatus to another.

### CONCLUSION

All grounds of rejection and objection of the Office Action of May 18, 2004 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the Claims should be allowed. Should the Examiner have any questions, or if a telephone conference would aid in the prosecution of the present application, Applicants encourage the Examiner to call the undersigned collect at 608-218-6900.

Dated: January 18, 2005

  
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Tanya A. Arenson  
Registration No. 47,391

MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
608/218-6900